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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,616	10/23/2003	Fujio Suzuki	SHX 333	5740

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EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,616	SUZUKI ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 7-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 7 and 9-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting of production of MCP-1, does not reasonably provide enablement for an infection control or for treatment or prevention of decreases in infection resistance as encompassed by claims 7 and 9-13 for the reasons set forth in the Office Action of September 16, 2004.

Applicant's arguments filed January 21, 2005 have been considered but have not been found persuasive.

Applicant contends that there is at least a reasonable correlation between the demonstrated ability to inhibit MCP-1 and the asserted utility of the recited glycyrrhizin derivatives. This argument has not been found persuasive since no evidence of reasonable correlation has been presented.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terminology "a compound according to any one of claims 1, 2, 3 and 8" renders claim 7 indefinite since claims 1, 2, 3 and 8 are method claims and not a compound claims.

Claims 1-3 and 8-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the European Patent No. 0 255 420 for the reasons set forth in the Office Action of September 16, 2004.

Applicant's arguments filed January 21, 2005 have been considered but have not been found persuasive.

Applicant contends that the European Patent does not disclose the treatment of entire organisms. This argument has not been found persuasive since the European Patent discloses on page 2, lines 25-29, that glycyrrhizin is an effective substance for the treatment of patients with AIDS. Therefore, the European Patent teaches the treatment of an entire organism.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent No. 0 255 420 for the reasons set forth in the Office Action of September 16, 2004.

Applicant's arguments filed January 21, 2005 have been considered but have not been found persuasive.

Applicant contends that the European Patent fails to teach a pharmaceutical composition according to claim 7. This argument has not been found persuasive because the European Patent discloses pharmaceutical compositions of glycyrrhizin on page 10, lines 6-14 i.e. the European Patent discloses oral, subcutaneous and intravenous solutions containing an effective amount of glycyrrhizin. Further note that a claim to a composition containing old chemical compound and solvent for compound is not patentable. Recital of solvent is unpatentable limitation. The effective ingredient, chemical compound, is still old and that it is carried by a solvent or diluent does not change the effective character of the compound. Ex parte Billman, 71 USPQ 253. Claims 1-3 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takei et al (Abstract T-14, ASM 101 st General Meeting, 5/22/2001).

Takei discloses hat Glycyrrhizin is effective in inhibiting MCP-1 and discloses that MCP-1 has been reported to stimulate the HIV replication. Therefore, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to use glycyrrhizin for the treatment of mammals in need of inhibiting of MCP-1 and f mammals having HIV infection.

Applicant's arguments filed January 21, 2005 have been considered but have not been found persuasive.

Since MCP-1 inhibition with glycyrrhizin in vitro was well known in the art at the time the instant invention was made as disclosed by Takei et al, MCP-1 inhibition in vivo would have been prima facie obvious to a person having ordinary skill in the art at he time the instant invention was made.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200